भारतीय मानक
Indian Standard

IS 17407 : 2020

डिजिटल ओटोस्कोप — हैंडहेल्ड टाइप

Digital Otoscope — Handheld Type

ICS 11.040.55

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June 2020 **Price Group 3**

Ear, Nose and Throat Surgery Instruments Sectional Committee, MHD 04

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Ear, Nose and Throat Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This Indian Standard specifies the general functional requirements of ‘digital otoscope — handheld type’. These are custom designed screening devices with application based software that enables the users (including semi-skilled technicians or community health workers) to store and share patient’s symptoms, treatment history, preliminary diagnosis and tympanic membrane images with healthcare providers for final diagnosis and treatment.

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

DIGITAL OTOSCOPE — HANDHELD TYPE

1 SCOPE

1.1 This Indian Standard provides general functional requirements of a digital otoscope — handheld type. It applies to otoscope that is portable, battery operated and has a display screen with suitable software to capture, store and transfer images to examine the external auditory canal and the tympanic membrane of human ear.

1.2 This standard does not apply to a wall mounted Otoscope.

2 REFERENCE

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No./ Other Publication	*Title*
988 : 1959	General requirements for optical components
13450 (Part 1) : 2018 / IEC 60601-1 : 2012	Medical electrical equipment: Part 1 General requirement for basic safety and essential performance
13450 (Part1/Sec 2) : 2018 / IEC 60601-1-2 : 2014	Medical electrical equipment: Part 1 General requirements for the safety, Section 2 Collateral standard — Electromagnetic compatibility — Requirements and tests (*first revision*)
IEC 60601-1-11 : 2015	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IS/IEC 62133-2 : 2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications: Part 2 Lithium systems
IS/IEC 62209-1 : 2016	Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices: Part 1 Devices used next to the ear (Frequency range of 300 MHz to 6 GHz)
IS/IEC 62304 : 2006	Medical device software — Software life cycle processes

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following terms and definitions shall apply.

3.1 Adaptor — A wired charger used to charge the battery of the device.

3.2 Device Body — A plastic enclosure that houses the display screen, electrical circuit and batteries

3.3 LED Circuit — A unit that provides light required for image capturing, storing and displaying the images.

3.4 Lens Assembly — A unit that houses the lenses to provide the required focus for capturing the images.

3.5 Software Application — A suitable application that is installed in the device and is used to capture screening data and images of the external auditory canal and the tympanic membrane and record/transfer the digitized images in a data form.

3.6 Speculum — The part of the otoscope that is inserted into the ear.

4 GENERAL REQUIREMENTS

4.1 Each part of the digital otoscope shall be made from materials of suitable strength and shall be suitably finished.

4.1.1 Coating and plating on each part shall be durable to resist discoluoration, wear and corrosion.

4.1.2 The device shall be of robust construction, operable by semi-skilled users.

4.1.3 The casing of the battery (mobile/LED) shall be sealed to prevent leakage and ingress of liquid into the instrument.

4.2 The optical parts shall be clear of fog and molds and conform to IS 988 : 1959.

4.3 The minimum resolution of the image shall be 640 x 480 pixels.

4.4 The device shall have provision for sharing the captured images through internet to health care provider through suitable transmission mode.

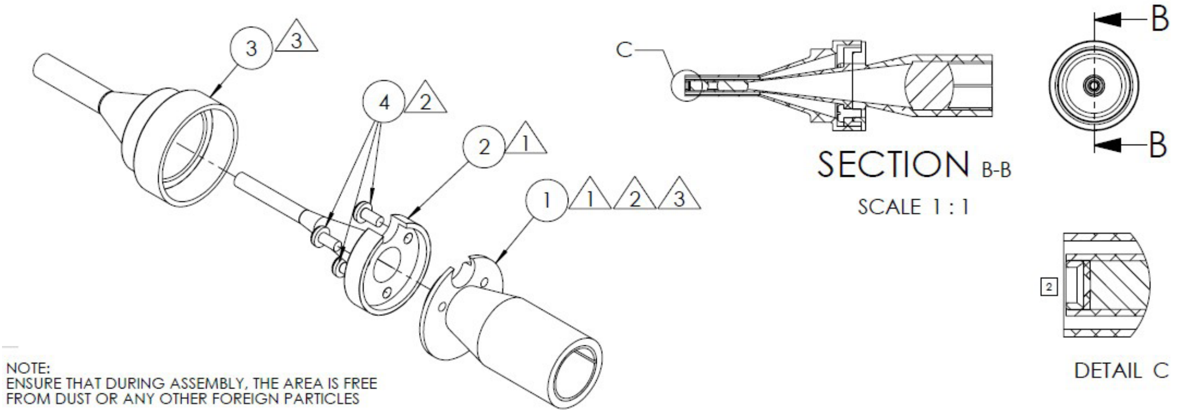
4.5 There shall be provision for storage of minimum 1 000 captured images.

4.6 The shape, size and weight of the device shall be user friendly and easy to handle and carry.

NOTE — An illustrative sketch of sub-assemblies of digital otoscope handheld type is presented in Fig. 1.

5 FUNCTIONAL REQUIREMENTS

The essential parts of the device shall meet the following requirements:



NOTE:
ENSURE THAT DURING ASSEMBLY, THE AREA IS FREE FROM DUST OR ANY OTHER FOREIGN PARTICLES

Fig. 1 a) Optics Assembly

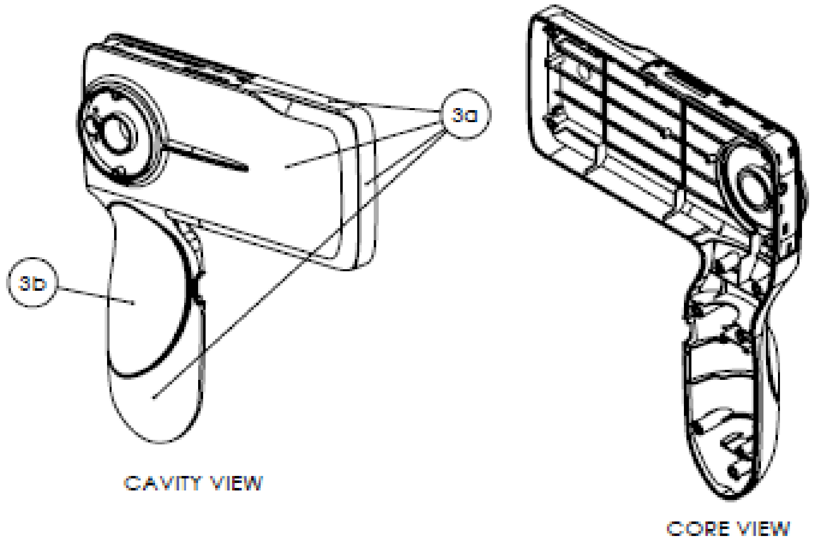


Fig. 1.b) Plastic Enclosures

Fig. 1 Illustrative Sketch of Sub-Assemblies of Digital Otoscope - Handheld Type

5.1 Device Body

The digital otoscope body shall have rigid enclosures to house the display screen, the electrical circuit to power the LED, the lens assembly and battery.

5.1.1 The device body shall have a textured handle to provide the grip required for proper operation.

5.1.2 The recommended source of light for imaging is LED with white light output not less than 1.3 lumens per watt. The device shall have an LED on/off and intensity control switch to operate the LED. The illumination at the tip of the speculum can be uniform and bright (not yellow).

5.1.3 The device shall have a robust touchscreen to facilitate navigation through the software application for screening and image capturing.

5.1.4 The device shall have Bluetooth or other interface capability to connect to accessories, such as a Bluetooth printer to print patient receipts.

5.1.5 The device shall comply with the general and electromagnetic compatibility requirements of IS 13450 (part 1) / IEC 60601-1 and IS 13450 (part 1 / Sec 2)/ IEC 60601-1-2.

5.1.6 The device shall comply to requirements of medical electrical equipment and medical electrical systems used in the home healthcare environment as per IEC 60601-1-11.

5.2 Lens Assembly

5.2.1 The lens assembly shall house three optical lenses to provide the required focus and clarity for image capture. The magnification of the lens can be 3X (approx) and a working distance of 83 mm.

5.2.2 The lens assembly shall be robustly fit over the camera on the device body.

5.2.3 The lens assembly shall be covered with a disposable speculum during screening of the external auditory canal and tympanic membrane of the patient.

5.2.4 The speculum shall be for single use only and shall be soft with no sharp edges.

5.2.5 The speculum shall be made of material that does not cause any injury or skin irritation to the patient when in contact during screening

5.2.6 The dimensions of the lens assembly shall be such that when inserted into the patient’s ear for screening, it maintains enough distance in the ear canal without causing any injury to the patient.

NOTE — For further guidance, refer IS 988 :1959

5.3 Battery and Charging

5.3.1 The device circuit battery in the device enclosure shall be compliant to IS/IEC 62133-2.

5.3.2 The casing of the battery shall be sealed to avoid leakage.

5.3.3 The device shall not produce any electrostatic discharge while connected to the charger or out in the field.

5.3.4 The device shall have a port for charging. The device shall indicate the status of display screen battery charging and LED battery charging while connected to the supply mains through the adaptor.

5.4 Application Based Software

5.4.1 The software shall be installed on the device as an application and shall be accessible through the app icon on the home screen.

5.4.2 The software shall support an android operating system compatible with the device.

5.4.3 The home screen, application launcher and the application based software shall be duly secured with a password protection feature.

5.4.4 The software may be made accessible on a mobile device and web portal with restricted login features.

5.4.5 The software shall be able to record duly secured data relating to patient details, patient complaints and capture images of the patient ear condition.

5.4.6 The software may also be a cloud-based application duly secured that can upload the patient screening images and information.

NOTE — For further guidance, refer IS/ISO 62304 : 2006.

6 ACCESSORIES

6.1 Adaptor — An adaptor may be provided to charge the device. The device shall only be used with the adaptor provided/ recommended.

6.2 Bluetooth Printer — The device shall be compatible with a Bluetooth enabled printer with a provision to print patient receipts after completion of the screening.

7 TESTS

7.1 The device shall conform to the requirements of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices as per IEC 62209-1 : 2016.

7.2 Light Output

The light output of the lamp shall be measured by a suitable photometer (Lumen meter). The measured value shall conform to the value specified in **5.1.2**.

7.3 Drop Test

The device when dropped from a height of 1.0 meters shall not show any signs of cracks or visible defects and the device shall operate satisfactorily after the test.

8 MARKING

8.1 Each portable smart otoscope shall be marked with the following:

a) Manufacturer's name/ trademark,
b) Name and address of the manufacturer,
c) Name and address of the marketer,
d) Month and Year of manufacture, and
e) Unique Device Identification / serial number.

8.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

9 PACKING

The device and its accessories shall be packed in a case in such a way that they are intact in the case.

9.1 The case for the device shall be made of a suitable material. It shall be so designed that when the device and accessories are kept in position and the lid is closed, there shall be no rattling inside the case.

9.2 Drop Test after Packing

The packed device when dropped on a hard surface from a height of 1.5 m shall show no sign of damage and shall operate satisfactorily after the test.

ANNEX A

(*Foreword* **)**

COMMITTEE COMPOSITION

Ear, Nose and Throat Surgery Instruments Sectional Committee, MHD 04

Organization(S)	*Representative(s)*
All India Institute of Medical Sciences, New Delhi (Others)	Dr Rakesh Kumar (***Chairman***)
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Jaggi Medical Instruments Co Pvt Ltd, Allahabad (Manufacturer)	Shri Tarun Jaggi Nomination Awaited (*Alternate*)

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Scientist ‘C’ (MHD), BIS

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This Indian Standard has been developed from Doc No.: MHD 04 (14136).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi